Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating regulations pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied

by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of

subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to human health or the environment, in which case no prior notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), (9), or (10) of subsection (e), no prior notification shall be necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Chemical Safety Improvement Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such regulations applicable to those claims as the Administrator may promulgate after the date of enactment of the Chemical Safety Improvement Act.".

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any regulation promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any regulation promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any regulation promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a regulation or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS AND ENTITIES.—An [organization or entity] that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by another individual may not be attributed to the defendant.".

SEC. 18. ~~PREEMPTION~~ STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c) and (d) **and subject to paragraphs (2) and (3)**, no State or political subdivision of a State may establish or continue to enforce ~~[~~any of the following:~~[Legis. Counsel note: this phrase and the colon have been inserted here and in subsection (b) to comply with formatting conventions regarding the use below of provisions with headers.]]~~

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require ~~for~~ the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) ~~for a substance~~ found to meet the safety standard and consistent with the scope of the determination made under section 6; ~~[~~or~~]~~

"(ii) ~~for a substance~~ found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) ~~EFFECTIVE DATE FOR~~ **SCOPE OF** CERTAIN PREEMPTION.—Under this subsection, Federal preemption **provided under paragraph (1)(B)** of State statutes and administrative actions applicable to specific substances shall ~~be consistent with the scope of the~~ **apply only to the uses or conditions of use of such substances that are included in the scope of the safety** determination made by the Administrator ~~and~~ **for the substance, and of any rule the Administrator promulgates pursuant to section 6(d).**

"(3) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the ~~date of the Administrator's determination that the substance meets the safety standard or until the date on which compliance with the rule issued under section 6(d) is required.~~ **effective date of the applicable action described in paragraph (1) taken by the Administrator.**

"(b) New Statutes or Administrative Actions Creating Prohibitions or Restrictions.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish (after the date of enactment of the Chemical Safety Improvement Act) **a**~~[any of the following:]~~

~~"(1) High priority.—A~~ statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance ~~identified~~ **designated** under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.

~~"(2) Low priority.—A statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a low-priority substance identified under section 4A, as of the date on which the Administrator designates the substance as a low priority.~~

"(c) Exceptions.—

"(1) ~~[IN GENERAL].—SUBSECTIONS~~ **IN GENERAL.—Subsections** (a) and (b) shall not apply to a ~~requirement, prohibition, or restriction~~ **statute or administrative action** of a State or a political subdivision of a State ~~that—[Legis. Counsel note: Generic header was added here and in paragraph (3) to ensure consistency with paragraph (2), which was given a header in client specs]~~ **applicable to a specific chemical substance that—**

"(A) is adopted under the authority of**, or authorized to comply with,** any other Federal law;

"(B) implements a reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that —~~**, unless that action taken by the State or political subdivision of a State—**

~~"(i) does not impose~~**"(i) imposes** a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) ~~is not otherwise required by or inconsistent with an~~ **(I) is already required by an action by the Administrator under section 5 or 6;**

"(II) is taken to address the same specific human health or environmental concern as an action taken by the Administrator under section 5 or 6 but is inconsistent with the action of the Administrator; or

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, ~~requirement,~~ standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any regulation, ~~requirement,~~ standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **under the authority of,** or authorized to comply with**,** any other Federal law;

"(B) implements **a** reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that does not impose~~**, unless that action taken by the State or political subdivision of a State—**

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance ~~and is not otherwise required by or inconsistent with an~~ **; and**

"(ii)(I) is already required by an action by the Administrator under section 5 or 6;

"(II) is taken to address the same specific human health or environmental concern as an action taken by the Administrator under section 5 or 6 but is inconsistent with the action of the Administrator; or

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(3) ~~[~~RULE OF ~~CONSTRUCTION]. NOTHING~~ **CONSTRUCTION.—Nothing** in this section shall be construed as requiring the Administrator to modify or withdraw, any rule or order under section 5 or 6 of this Act, or as modifying the effect of this section as enacted prior to the effective date of the Chemical Safety Improvement Act on any rule or order promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

"(d) Preservation of Certain State Law.—Nothing in this section shall be construed to preempt or otherwise affect any ~~warning requirement relating to consumer products or substances that is~~ **statute or administrative action that prohibits or restricts chemical manufacturing, processing, distribution in commerce, or use** established pursuant to State law that was in effect on ~~August 31, 2003, unless a rule, consent agreement, or order is promulgated under section 6 imposing a warning requirement, which shall preempt a chemical specific State warning requirement consistent with the scope of the Administrator's determination under section 6.~~ **January 1, 2015.**

"(e) State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator ~~may provide a waiver~~ **may—**

"(A) by rule, exempt from subsection (a) ~~and subsection (b)(1), regarding~~**, under such conditions as may be prescribed in the rule,** a statute or administrative action of that State or political subdivision of the State that relates to the effects **of,** or exposure to ~~any~~**, a** chemical substance under the intended or reasonably anticipated conditions of use **if** ~~if—~~

~~"(A)(i) the State or political subdivision of the State determines it cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination established under section 3A; and~~

~~"(ii)~~ the Administrator determines that—

~~"(I)~~**"(i)** compelling State or local conditions warrant granting the waiver to protect human health or the environment;

~~"(II)~~**"(ii)** compliance with the proposed requirement of the State or political subdivision of the State ~~will~~ **would** not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

~~"(III)~~**"(iii)** compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science; **or**~~"(B)(i) the Administrator finds a safety assessment or~~

~~determination has been unreasonably delayed; and~~

~~"(ii) the State certifies that—~~**"(B) exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the intended or reasonably intended conditions of use if the Administrator determines that—**

~~"(I)~~**"(i)** the State has a compelling local interest **that warrants granting the waiver** to protect human health or the environment;

~~"(II)~~**"(ii)** compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

~~"(III)~~**"(iii)** compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** the proposed requirement is grounded in reasonable scientific concern~~; or~~

~~"(C)(i) the State has contracted with the National Academy of Sciences to assess the hazard, use and exposure, and risk of a chemical substance;~~

~~"(ii) the report complies with the requirements of the Federal Advisory Committee Act Amendments of 1997; and~~

~~"(iii) based on the best available evidence described in the report of the National Academy of Sciences, the State establishes a requirement relating to the effects of or exposure to a chemical substance~~.

"(2) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver application—

"(A) not later than 180 days after the date on which an application under paragraph (1)(A) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (1)(B) is submitted.

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(5) DURATION OF WAIVERS.—A **waiver** ~~waiver—~~

~~"(A)~~ granted under paragraph **(1)(B)**~~(1)(A) shall remain in effect unless the waiver is found to be in conflict with a completed safety assessment and determination; and~~

~~"(B) granted under [subparagraph (B) or (C) of paragraph (2)]~~ shall remain in effect until **the later of—**

"(A) such time as the safety assessment and determination is completed**; and**.

~~"(6) Judicial review.—~~**"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.**

~~"(A) In general.—Not~~**"(6) JUDICIAL REVIEW.—Not** later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under **subparagraph (A) or (B) of** paragraph (1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

~~"(B) Judicial review of prioritization screening decision.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(c) to designate a chemical substance as a low priority, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation, as applicable, may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.~~

"(7) SAVINGS.—

"(A) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision in this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any state, maritime, or Federal common law or statutory theory.

"(C) NO EFFECT ON PRIVATE REMEDIES.—

"(i) Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(ii) This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d)(4), 6(d), or 8"; and

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting ["a regulation promulgated pursuant to section 6(d)"]; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)—

(A) in subparagraph (B)—

(i) in clause (i)—

(I) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 5(d)(4), or 6(d)"; and

(II) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(ii) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the regulation, except as part of the rulemaking record, taken as a whole."; and

[(B) by striking subparagraph (C).]

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a regulation pursuant to section 4, 5(d), 6(b), 6(c), 6(d), or 8 or an order issued under section 4 or 5(d), the petitioner shall be provided an

opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a regulation or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4 or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a regulation under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a regulation under section 8, there is a reasonable basis to conclude that the regulation is necessary to protect human health or the environment from an unreasonable risk of harm to human health or the environment.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to human health or the environment alleged by the petitioner is less than the extent of risks to human health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26 ~~(e) of the Toxic Substances Control Act (15 U.S.C. 2625(e)) is amended~~ **of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—**

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) submits a notice pursuant to the rule promulgated under section 8(b)(4) identifying a chemical substance as active;

"(ii) submits a notice pursuant to section 8(b)(5)(E)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

"(iv) manufactures or processes a chemical designated by the Administrator as a high-priority substance pursuant to section 4A(b).

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to make determinations for chemical substances under section 5(c)(3) and impose and necessary restrictions under section 5(c)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) take into account the cost to the Administrator of conducting the activities

described in paragraph (2);

"(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray a portion of the costs of conducting the activities identified in that paragraph, not to exceed [__] percent of the cost of conducting the activities described in paragraph (2)(A);

"(D) establish appropriate criteria for manufacturers or processors that results in a proportionate assessment of fees;

"(E) for substances designated as additional priorities pursuant to section 4A(d), establish the fee at a level sufficient to defray the costs to the Administrator of conducting the safety assessment and safety determination under section 6;

"(F) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, shall accrue with respect to such meetings;

"(G) beginning with the fiscal year that is 3 years after the date of enactment of the Chemical Safety Improvement Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient and not more than reasonably necessary to defray the portion of the costs specified in subparagraph (C) of conducting the activities identified in paragraph (1);

"(ii) to account for inflation; and

"(iii) to minimize, to the maximum extent practicable, shortfalls in or an accumulation of unused amounts in the Fund established by paragraph (4)(A);

"(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(I) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (1);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this paragraph shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this section shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead allocation of costs associated with the conduct of the activities described in paragraph (1).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is [10/15] years after the date of enactment of the Chemical Safety Improvement Act, unless otherwise reauthorized or modified by Congress."; and

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS.

Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking

paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a regulation, testing consent agreement, or order under section 4;".

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended by striking "Except as provided in section 4(f), this" and inserting "This".

Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Chemical Safety Improvement Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(a) of the Toxic Substances Control Act (15 U.S.C. 2601(a)) is amended—

(1) in paragraph (2)—

(A) by striking "injury" and inserting "harm"; and

(B) by striking "and" at the end;

(2) by redesignating paragraph (3) as paragraph (4); and

(3) by inserting after paragraph (2) the following:

"(3) reform of this Act in accordance with the amendments made by the Chemical Safety Improvement Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief; and".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (7), (8), (9), (10) , (11), (12), (13), and (14) as paragraphs (9), (10), (11), (13), (14), (19), (20), and (21), respectively;

(2) by inserting after paragraph (6) the following:

"(7) INFORMATION.—The term 'information' means any qualitative, quantitative, or descriptive facts, data, analysis, or assessment related to chemical hazards, use, or exposure (including the nature and extent of exposure to a chemical substance), including from health and safety studies.

"(8) INTENDED OR REASONABLY ANTICIPATED CONDITIONS OF USE.—The term 'intended

or reasonably anticipated conditions of use' means the circumstances the Administrator determines are those under which a chemical substance is intended, reasonably known, or reasonably anticipated to be manufactured, processed, distributed in commerce, used, and disposed of.";

(3) by inserting after paragraph (11) (as so redesignated) the following:

"(12) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the intended or reasonably anticipated conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (14) (as so redesignated) the following:

"(15) PUBLICLY AVAILABLE.—

"(A) IN GENERAL.—The term 'publicly available', with respect to information, means information that is—

"(i) generally accessible and available to the general public; or

"(ii) in the public domain.

"(B) INCLUSIONS.—The term 'publicly available', with respect to information, includes information that has been published in periodicals, books, print, an electronic format, or other media available for general distribution to any member of the public.

"(16) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the intended or reasonably anticipated conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(17) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use.

"(18) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably anticipated conditions of use, including no unreasonable risk of harm to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of

Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating to the hazards and exposures of a chemical substance under the intended or reasonably anticipated conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any regulation, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of human health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical

substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential human health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other

information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by regulation, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to identify the hazards, exposures, intended or reasonably anticipated conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for those identifications; and

"(cc) to accept comments regarding the identifications; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the intended or reasonably

anticipated conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on human health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies; and

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop guidance to assist interested persons in developing draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft assessment for consideration by the Administrator.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "regulation, testing consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(f), the Administrator may require the development of test data and information described in paragraph (1) or (2) by—

"(A) promulgating a regulation;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A regulation, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a regulation, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the regulation, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time

is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a regulation or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the

development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used in safety assessments and safety determinations under section 6 that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) beginning on the date that is 5 years after the date of enactment of the Chemical Safety Improvement Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(C) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any safety assessment or safety determination under section 6.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the regulation, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180

days after the end of the period described in this section.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a regulation, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the regulation, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by regulation, a risk-based screening process and explicit

criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the regulation under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances and low-priority substances; and

"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.

"(B) REQUIREMENTS.—The initial list of substances shall contain at least 10 high-priority substances and at least 10 low-priority substances.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance

removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(III) LOW-PRIORITY SUBSTANCES.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final regulation under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a regulation, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances

appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including specific scientific classifications and designations by authoritative governmental entities;

"(C) the intended or reasonably anticipated conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a regulation promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the applicable safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a regulation, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

"(8) REVISION BASED ON NEW INFORMATION.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on new information made available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Chemical Safety Improvement Act, a State enacts a statute or takes an administrative action to restrict or prohibit the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the intended conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the restriction or prohibition, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a restriction or a prohibition under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or subject a State to section 15.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Expedited Prioritization Screening Requested by States.—

"(1) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives from the Governor of a State or a State agency with responsibility for protecting health and the environment a recommendation and relevant information justifying that a substance be designated under paragraph (3) or (4) of subsection (b) as a high-priority substance or a low-priority substance, the Administrator shall make a prioritization screening decision for the substance.

"(2) LIMITATION.—The Governor of a State or a State agency with responsibility for protecting health and the environment may annually recommend not more than 2 chemical substances for prioritization screening under paragraph (1).

"(3) RECOMMENDATION.—Notwithstanding subsection (b)(8), a recommendation by the Governor of a State or a State agency with responsibility for protecting health and the environment with respect to a chemical substance that has been previously prioritized shall not be required to be based on new information.

"(4) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment regarding the recommendations submitted under this subsection.

"(5) EXPLANATION OF REASONS.—The Administrator shall—

"(A) make available to the Governor or State agency, as applicable, and to the public a brief explanation of the reasons for—

"(i) identifying a chemical substance recommended by the Governor or State agency for prioritization screening as a high-priority substance or a low-priority substance; or

"(ii) deferring a prioritization screening decision; and

"(B) identify the information relied on in making that identification.

"(d) Additional Priorities for Safety Assessments and Determinations.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance, or that has not been subject to or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E); and

"(B) provide guidance to submitters on the information to be provided in such requests, and specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under

this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) not more than 15 percent of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(h) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).

"(e) Treatment.—An action by the Administrator under this section shall not be—

"(1) considered to be a final agency action; or

"(2) subject to judicial review.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW

USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding intended or reasonably anticipated conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date

of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and based on the information described in paragraph (2), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (5);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b), the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a regulation pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the

restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or restriction under subparagraph (A) may include, as appropriate—

"(i) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(ii) a requirement that manufacturers and processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other regulation of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other appropriate restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or restriction under this subsection to address workplace exposures.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a regulation, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.

"(6) REGULATION PENDING DEVELOPMENT OF INFORMATION.—Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes of a chemical substance to commence pending receipt of the additional information, subject to compliance with any restrictions under paragraph (4) determined by the Administrator to be sufficient to ensure that the chemical substance is likely to meet the safety standard.

"(7) COMMENCEMENT OF MANUFACTURE.—Subject to paragraphs (4), (5), and (6), at the end of the applicable period for review under paragraph (1), the submitter of a notice under subsection (a) may commence manufacture for commercial purposes of a chemical substance or a chemical substance for a significant new use.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer or processor that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer or processor shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer or processor; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, regulations, and orders of the Administrator; and

"(2) all information submitted or issued under this section.";

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4),"; and

(11) by adding at the end the following:

"(i) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section before the date of enactment of the Chemical Safety Improvement Act.".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (h) and (i), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(3) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(4) shall promulgate a final regulation pursuant to subsection (d) by not later than 2

years after the date on which the safety determination is completed; and

"(5) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (3) and (4) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Chemical Safety Improvement Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or regulation solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or regulation shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by regulation under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-

priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a regulation, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Regulation.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a regulation establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—The regulation promulgated pursuant to this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate; and

"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which—

"(i) shall be as soon as practicable; and

"(ii) as determined by the Administrator, may vary for different affected persons.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or restriction under this subsection to address workplace exposures.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers and processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any regulation under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other regulation regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to restrict, ban, or phase out, or any other regulation of, any method of commercial use of the chemical substance;

"(G) a requirement to restrict, ban, or phase out, or any other regulation of, any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of unreasonable risks of harm to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a regulation under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a regulation under paragraph (1), the

Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a regulation under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a regulation promulgated under paragraph (1) if the Administrator determines that—

"(i) the regulation cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to human health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a regulation under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a regulation under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the intended or reasonably anticipated conditions of use if the regulation is promulgated.

"(E) CONDITIONS.—As part of a regulation promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect human health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a regulation under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by regulation, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a regulation requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed regulation under subsection (d) to be effective on publication of the regulation in the Federal Register and until the effective date of final action taken respecting the regulation, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed regulation or any combination of those activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed regulation so effective is necessary to protect the public interest; and

"(2) in the case of a proposed regulation to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final regulation promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final regulation.";

(4) in subsection (h) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4); and

(5) by adding at the end the following:

"(j) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act.".

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) REGULATION, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a regulation, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) REGULATIONS.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall promulgate regulations requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including regulations requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR REGULATIONS.—In carrying out this subparagraph, the Administrator may modify, as appropriate, regulations promulgated before the date of enactment of the Chemical Safety Improvement Act.

"(B) CONTENTS.—The regulations promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting requirements on manufacturers and processors;

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported; and

"(iii) shall apply only in cases in which the Administrator determines that the submission of reports would assist in the effective implementation of this Act.

"(C) ADMINISTRATION.—In implementing this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the regulations on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the regulations promulgated under this subsection.";

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Chemical Safety Improvement Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) REGULATIONS.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator, by regulation, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the regulation, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the

Chemical Safety Improvement Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The regulation promulgated by the Administrator pursuant to subparagraph (A) shall require—

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a regulation that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for

a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(F) LIMITATION.—The specific identity of any chemical substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

"(G) CERTIFICATION.—The regulation under this subsection shall require a manufacturer or processor—

"(i) to certify the accuracy of each report of the manufacturer or processor carried out under the regulation; and

"(ii) to retain a record supporting that certification for a period of 5 years beginning on the last day of the submission period.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances

designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

"(ii) the regulations promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

"(I) IN GENERAL.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(aa) in the notice submitted under clause (i), assert the claim; and

"(bb) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(II) LIMITATION.—The specific identity of any inactive substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2);

and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the regulation required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Chemical Safety Improvement Act, as the initial list of active substances for the purposes of section 4A.

"(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to human health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section: